

Caldera Medical, Inc. T-Sling

K050516.5

510(k) Summary

FEB 3 2006

Date of Summary: January 19, 2006

Applicant: Bryon L. Merade, CEO
Caldera Medical, Inc.
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Agoura Hills, CA 91301
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Contact: Marla Kengen, Project Leader
Caldera Medical, Inc.
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marla@calderamedical.com

Device Name: Surgical Mesh (878.3300)

Trade Name: T-Sling

Common Name: Surgical Mesh

Classification: Class II

Predicate Devices: Herniamesh T-Sling – K020652
Tyco Healthcare IVS Tunneller – K010035
Ethicon TVT – K012628

Device Description: The T-Sling is made of monofilament polypropylene warp knitted into composite mesh construction. The T-Sling is a sterile, single-use pubourethral sling for the treatment of stress urinary incontinence (SUI).

Indications for Use: The T-Sling is intended to be used in females to position a mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

Ms. Marla Kengen
Project Leader
Caldera Medical, Inc.
28632 Roadside Drive, Suite 260
Agoura Hills, California 91301

Re: K050516
Trade/Device Name: T-Sling
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: November 28, 2005
Received: December 19, 2005

Dear Ms. Kengen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

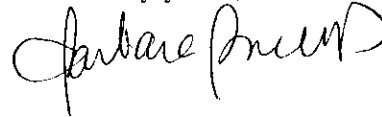
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with the first name "Mark" being the most prominent.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number: K050516

Device Name: T-Sling

Indications For Use:

The T-sling is intended to be used in females to position a polypropylene mesh for treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)

Barbara Friedman
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K050516